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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

MARIA E. BARRAZA, KAREN BLACK, THOMAS FLOURNAY, JAMES HOLT, GREGORY LESTER, ~~KEVIN MEEKS,~~ EDDIE MIMS, NANCY MOSHER, DELMAR LEE PECK, DENISE TOMLIN, LINDA WALKER, and DIANE WASHINGTON

Plaintiffs,

v.

C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

Case No. CV16-cv-01374-PHX DGC

~~SECOND~~THIRD AMENDED CLASS ACTION COMPLAINT

For their Second Amended Complaint against C.R. Bard, Inc. and Bard Peripheral Vascular, Plaintiffs Maria E. Barraza, Karen Black, Thomas Flournay, James Holt, Gregory Lester, ~~Kevin Meeks,~~ Eddie Mims, Nancy Mosher, Delmar Lee Peck, Denise Tomlin, Linda Walker, and Diane Washington allege as follows:

Introduction

1. This is a class action to allow Plaintiffs and Class members (defined below) to seek and receive appropriate diagnostic services and other declaratory relief that they require as a direct and proximate result of the negligent and wrongful misconduct of Defendants in connection with the development, design, promotion, marketing, and sale of certain inferior vena cava ("IVC") filters.

2. Defendants have designed, marketed, and sold IVC filters that were negligently and defectively designed and for which Defendants have failed to provide adequate information and warnings regarding their safety, effectiveness, and failure rates.

3. Defendants' IVC filters are prone to break into parts (fracture) such that struts break away from the device and ultimately can become lodged in a vein, artery, or even an organ, such as the heart or lungs. The filters also tend to break loose from the point of implantation and to migrate to other locations in the bloodstream or to become lodged in the heart or lungs. The filters further have a significant chance of tilting within the IVC, perforating the vena cava and/or causing the formation of blood clots.

4. Any and all of these adverse events have the potential of causing serious and life threatening medical conditions for patients implanted with the IVC filters. In so doing, they significantly increase the risks of injury and death for those patients.

5. However, many of these conditions can be asymptomatic in the patient prior to the manifestation of significant and sometimes fatal injuries.

6. Each and every Plaintiff and Class Member will be better off knowing the state of their IVC filter, including its present condition and position. The notice plan and diagnostic program described below will arm Plaintiffs and Class members and their doctors with the knowledge they need to take steps to protect themselves from future harm.

7. The devices at issue have injured Plaintiff and the Class. These devices are potential ticking time bombs implanted in unsuspecting patients. The harm suffered by these patients exists as a result of the design defects inherent in the device such that patients and doctors are unsure of

safety of the current state of the device. Each patient is in need of a diagnostic test to determine what is the safest course of medical action to deal with the flawed device.

8. The relief that Plaintiffs seek on their own behalf and on behalf of the Class is consistent with the Food and Drug Administration's ("FDA") conclusion, described below, that physicians should consider removal as soon as a patient's transient risk for pulmonary embolism has passed, and will allow Plaintiffs and the healthcare community to effectuate the FDA's guidance. This case presents a simple question: who should pay for the diagnosis and testing that the FDA has stated is needed for the Class?

Parties

9. Plaintiff Maria E. Barraza is a resident of the state of Florida. She was implanted with a Bard G2 Express filter in August 2008. The filter has not been explanted.

10. Plaintiff Karen Black is a resident of the state of California. She was implanted with a Bard Eclipse filter on October 16, 2011. The filter has not been explanted.

11. ~~10.~~ Plaintiff Thomas Flournay is a resident of the state of Colorado. He was implanted with a Bard Recovery filter on June 9, 2005. The filter has not been explanted.

12. ~~11.~~ Plaintiff James Holt is a resident of the state of Arizona. He was implanted with a Bard Eclipse filter on July 31, 2012. The filter has not been explanted.

13. ~~12.~~ Plaintiff Linda Walker is a resident of the Commonwealth of Pennsylvania. She was implanted with a Bard G2 filter on April 4, 2011. The filter has not been explanted.

14. ~~13.~~ Plaintiff Gregory Lester is a resident of the state of West Virginia. He was implanted with a Bard Denali filter on February 6, 2014. The filter has not been explanted.

~~14. Plaintiff Kevin Meeks is a resident of the state of California. He was implanted with a Bard Meridian filter on February 4, 2013. The filter has not been explanted.~~

15. Plaintiff Eddie Mims is a resident of the Commonwealth of Massachusetts. He was implanted with a Bard Eclipse filter on August 20, 2014. The filter has not been explanted.

16. Plaintiff Delmar Lee Peck is a resident of the state of Missouri. He was implanted with a Bard Recovery filter in 2005. The filter has not been explanted.

17. Plaintiff Nancy Mosher is a resident of the state of Ohio. She was implanted with a Bard G2 filter on September 13, 2007. The filter has not been explanted.

18. Plaintiff Denise Tomlin is a resident of the state of Maryland. She was implanted with a Bard Denali filter on June 30, 2014. The filter has not been explanted.

19. Plaintiff Diane Washington is a resident of the state of Illinois. She was implanted with a Bard Denali filter on March 30, 2015. The filter has not been explanted.

20. Defendant C.R. Bard, Inc. ("Bard") is a citizen of the state of New Jersey and is authorized to do business in the state of Arizona and said Defendant was doing business in Maricopa County, Arizona. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold IVC filters, including the Recovery® Filter System, the Eclipse® Filter System, the G2 Filter System, the G2 Express System, the G2X System, the Meridian Filter System, and the Denali Filter System (collectively "IVC Filters"), to be implanted in patients such as Plaintiffs throughout the United States, including in the states for which Plaintiffs seek certification of statewide classes, as set forth below.

21. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of Defendant C.R. Bard, and is a citizen of the state of Arizona, is authorized to do business in the state of Arizona, and was doing business in the state of Arizona. BPV, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the IVC Filters described herein to be implanted in patients such as Plaintiffs throughout the United States, including in each of the states for which Plaintiffs seek certification of statewide classes, as set forth below.

Jurisdiction

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because this is a class action, filed under Rule 23 of the Federal Rules of Civil Procedure; there are hundreds, if not thousands, of proposed Class Members; the aggregate amount in controversy exceeds the jurisdictional amount or $5,000,000.00; and the Defendants are citizens

of a State different from that of Plaintiffs and the Class. This Court also has subject matter jurisdiction over Plaintiffs' and the proposed Class's claims pursuant to 28 U.S.C. § 1367(a).

23. Venue is proper in this Court pursuant to 28 U.S. C. § 1391, because at least one of the Plaintiffs resides in this district, and resided in this district at the time of implantation of the IVC filter, and because Defendants regularly conduct business here. Venue is also appropriate in this district for pretrial matters pursuant to order of the Judicial Panel on Multidistrict Litigation and 28 U.S.C. § 1407.

Background

A. IVC FILTERS

24. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

25. An IVC filter is a device that is designed purportedly to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the inferior vena cava.

26. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the inferior vena cava, and into the lungs or heart. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present serious risks to human health.

27. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE and who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

28. Even though IVC filters have been on the market for decades and were traditionally permanent implants, the use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

29. In order to increase sales of these devices, Bard sought to expand the market for prophylactic use among nontraditional patient populations that were temporarily at risk of developing blood clots.

30. Specifically, Bard targeted the bariatric, trauma, orthopedic, and cancer patient population. Expansion to these new patient groups would triple sales, and the first manufacturer to market would capture market share.

31. At the same, Bard physicians developed interest in filter devices that could be easily removed after the risk of clotting in these new patient populations subsided. This too was an opportunity to gain market share in the lucrative IVC-filter market.

32. Other manufacturers also saw this opportunity, triggering a race to market a device that provided physicians the option to retrieve the filter after the clot risk subsided.

33. Bard was the first medical device manufacturer to obtain FDA clearance for marketing a "retrievable" IVC filter (the Bard Recovery® filter) on July 25, 2003.

34. This "clearance" was obtained despite lack of adequate evidence on the safety and efficacy of the new line of devices.

THE RECOVERY® FILTER

A. Development and Regulatory Clearance of the Recovery® Filter

35. Bard has distributed and marketed the Simon Nitinol Filter ("SNF") device since 1992. The SNF is a permanent filter with no option to retrieve it after implantation.

36. The SNF was initially manufactured by a company known as Nitinol Medical Technologies. In late 1999, Bard worked with Nitinol on the redesign of the SNF in order to make it retrievable. On October 19, 2001, Bard purchased the rights to manufacture, market, and sell this new, redesigned product in development at the time. This product ultimately became the Recovery® filter.

37. Bard's purpose for making a retrievable IVC filter was to increase profits by expanding the overall IVC-filter market and, in turn, Bard's percentage share of that market.

38. Bard engaged in an aggressive marketing campaign for the filter, despite negative clinical data.

39. On November 27, 2002, Bard bypassed the FDA's more onerous approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the Recovery® filter as a *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the SNF.

40. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the new device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., which the court quoted from:

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA. *A pre-market notification submitted under 510(k) is thus entirely different from a PMA which must include data sufficient to demonstrate that the IVC Filters is safe and effective.*

376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

41. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly."

518 U.S. 470, 478-79 (1996) (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

42. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with the [product]. . . and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling . . . ." This obligation extends to post-market monitoring of adverse events/complaints.

43. On July 23, 2003, through this 510(k) process, Bard obtained clearance from the FDA to market the Recovery® filter for optional retrieval.

44. Although Bard began marketing the Recovery® filter in April 2003, full market release did not occur until January 2004.

45. Bard was aware that the Recovery® filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric (weight loss) and orthopedic procedures.

46. The Recovery® filter consists of two (2) levels of six (6) radially distributed NITINOL (a nickel titanium alloy whose full name is Nickel Titanium Naval Ordinance Laboratory) struts that are designed to anchor the filter into the inferior vena cava and putatively to catch any embolizing clots.

47. This filter has six short struts, which are commonly referred to as the "arms," and six long struts, which are commonly referred to as the "legs."

48. Each strut is held together by a single connection to a cap located at the top of the filter. According to the patent application filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

49. The alloy NITINOL possesses "shape memory," meaning NITINOL will change shape according to changes in temperature, then retake its prior shape after returning to its initial temperature.

50. When placed in saline, the Recovery® filter's NITINOL struts become soft and can be straightened to allow delivery through a small-diameter catheter. The NITINOL struts then resume their original shape when warmed to body temperature in the vena cava.

51. The Recovery® filter is inserted via catheter guided by a physician (normally an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion.

52. According to the Instructions for Use ("IFU") of this medical device, only the Recovery® Cone System could be used to retrieve the Recovery® filter (as well as subsequent generations of Bard's IVC Filters).

53. The Recovery® Cone System is an independent medical device requiring approval by the FDA under the pre-market approval process or, if a substantially equivalent medical device was already on the market, clearance by the FDA pursuant to the 510(k) application process.

54. Although Bard marketed and sold the Recovery® Cone System separately, it never sought or obtained approval or clearance from the FDA for this device until 2016.

55. Bard's sale of the Recovery® Cone System was, therefore, illegal.

56. Bard illegally sold the Recovery® Cone System in order to promote the Recovery® filter as having a retrieval option.

B. Post-Market Performance Revealed The IVC Filters Failed to Perform as Expected

57. Once placed on the market, Bard immediately became aware of numerous confirmed events where its Recovery® filter fractured, migrated, or perforated the inferior vena cava, caused thrombus and clotting, and caused serious injury, including death.

58. Premarket and post-market clinical trials revealed that the Recovery® filter failed and caused serious risks of harm. In addition, peer-reviewed literature reflected that such filters actually increased the risk of patients developing thromboembolitic events.

59. Approximately a month after the full-scale launch of the Recovery® filter, on February 9, 2004, Bard received notice of the first death associated with this filter. The next day, analysis was performed of the FDA's MAUDE adverse-events database which revealed that there had been at least two other migration-related adverse events reported to Bard in 2003.

60. MAUDE is a database maintained by the FDA to house medical device reports submitted by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such as health care providers and patients).

61. Instead of pulling the Recovery® filter off the market, Bard focused on public relations and protecting its brand and image. By February 12, 2004, Bard had formed a crisis communication team and drafted at least four communiques to pass onto its sales force containing false information designed to be relayed to concerned doctors.

62. By April of 2004, at least three deaths had been reported to Bard. Yet again, instead of recalling its deadly device, Bard concealed this information from doctors and patients and hired the public relations firm Hill & Knowlton to address anticipated publicity that could affect stock prices and sales.

63. Bard made the decision to continue to market and sell the Recovery® filter until its next generation product, the G2® IVC filter, was cleared by the FDA.

64. The G2® filter, however, was not cleared for market until August 29, 2005.

65. Meanwhile, the death count escalated.

66. On July 12, 2004, Bard CEO Timothy Ring received an executive summary reporting that there were at least 12 filter migrations resulting in four deaths and at least 17 reports of filter fracture, six cases of which involved strut embolization to the heart.

67. This same report advised that fracture rates for the Recovery® filter exceeded reported rates of other filters.

68. These events revealed, or should have revealed, to Bard that the Recovery® filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body.

69. Bard also learned that the Recovery® filter failed to meet migration resistance testing specifications.

70. In addition, multiple early studies reported that the Recovery® filter has a fracture and migration rate ranging from 21% to 31.7%, rates that are substantially higher compared to other IVC filters. More recently, fractures were reported to be as high as 40% after five and a half years from the date of implant.

71. Bard had clear evidence that the Recovery® filter was not substantially equivalent to the predecessor SNF, making the Recovery® filter adulterated and misbranded, requiring its immediate withdrawal from the market.

72. At least one Bard executive concluded the Recovery® filter posed an unreasonable risk of harm and required corrective action, including a recall.

73. Likewise, Bard's G2® filter was predicted to have fracture rates as high as 37.5% after five years from date of implant.

74. Subsequent Bard IVC Filter models, including the electropolished version of the G2® filter known as the Eclipse, only marginally increased fracture resistance.

75. When IVC filter fractures occur, shards of the filter or even the entire filter can travel to the heart, where they can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction, and/or death.

76. Bard IVC Filters similarly pose a high risk of tilting and perforating the vena cava walls. When such tilting occurs, the filters can also perforate the adjacent aorta, duodenum, small bowel, spine, or ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death.

77. The Adverse Event Reports ("AERs") associated with all IVC filters demonstrate that Bard IVC Filters are far more prone to failure then are other similar IVC filters. A review of the FDA MAUDE database from the years 2004 through 2008 shows that Bard IVC Filters are responsible for the following percentages of all IVC filter AERs:

a. 50% of all adverse events;

b. 64% of all occurrences of migration of the IVC Filters;

c. 69% of all occurrences of vena cava wall perforation; and

d. 70% of all occurrences of filter fracture.

78. These failures were often associated with severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

79. On information and belief, Bard's reporting of adverse events to the MAUDE database significantly understates the number of adverse events for Bard IVC Filters and the severity of injuries caused by their filters. These failures and resulting injuries are attributable, in part, to the fact that the Bard IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo* indicating that they pose an ever present and continuing unreasonable risk of harm.

80. In particular, each filter is constructed from Nitinol and utilizes a dual-level filtrations systems that consists of filter "struts." The surface of the Nitinol wire components is unreasonably rough and contains surface slip-band cracking and surface damage as a result of drawing and grinding during the refining of the raw Nitinol wire.

81. These filters were designed with surface gouges so that they could be manipulated during the build in order to accommodate the size and shape of the final product. Additionally, the inner corner of the sleeve where it connecting with the Nitinol struts was designed with a sharp, instead of a rounded inner corner. The result of this design choice creates a high stress point making the filters unreasonably prone to fracture and failure.

82. With respect to the initial testing and specifications of the filters at issue, Defendants' analysis to evaluate the stresses placed on the devices after implant was inadequate to properly determine their real world performance. In particular, Defendants did not consider the

stress loading impact of the struts incorporation into the walls of the vena cava sufficient to properly design a filter that would not fail after implantation.

83. In designing these filters, Defendants did not account for or properly design a weld process for the portion of the filter that binds the struts together such that it would not result in a sharp edge running parallel to the wire surface in order to minimize or eliminate device fracture.

84. The geometric design of these filters and struts encouraged unnecessary stress on the contact point between the wires and sheath of the filters as well as wire to wire contact such that unreasonable failure rates would likely result and this defect would subject the devices to unreasonably high levels of tilt after implantation as well as perforation of the vena cava wall. These implantation malfunctions significantly and unreasonably raise the injury risk for these devices.

85. The design of these filters failed to include a common wire element to connect the struts together, further increasing the likelihood of strut fracture, and device tilt and migration.

86. In addition to design defects, Bard IVC Filters suffer from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the filters.

87. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the Bard IVC Filters while in the body. In particular, the Recovery® filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the filters. These exterior manufacturing defects render Bard IVC Filters too weak to withstand normal placement within the human body.

88. Bard was aware that Bard IVC Filters had substantially higher reported failure rates than all other IVC filters for fracture, perforation, migration, and death. For example:

a. On April 23, 2004, Bard's Corporate VP of Quality Assurance sent an email noting that the Recovery® filter's reported failure rates "did not look good compared to permanent filters" and promised to remove the filter from the market if its reported death rate became "significantly greater than the rest of the pack."

b. On July 9, 2004, a BPV safety analysis of reported failure rates determined that the Recovery® filter had a reported failure rate that was 28 times higher than all other IVC filters.

c. On December 17, 2004, analysis determined that the "[r]eports of death, filter migration (movement), IVC perforation, and filter fracture associated with the Recovery® filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 times higher, respectively, than reporting rates for all other filters. . . . These deficiencies were all statistically significant . . . [and were] significantly higher than those for other removable filters."

d. By December 2004, according to BPV's own findings pursuant to its safety procedure, the Recovery® filter had so many reported failures that it was deemed not reasonably safe for human use and required "correction."

e. A BPV safety analysis from June 28, 2011, revealed that the Recovery® filter had a reported fracture rate 55 times higher than the SNF.

f. Whereas the Recovery® filter was reported to have caused over a dozen deaths by early 2005, the SNF has never — to Plaintiffs' knowledge — been reported as associated with a patient death. These facts were discussed internally while Bard continued to tout the effectiveness of these IVC Filters.

C. Defendants Knew Why the Recovery® Filter Was Failing and Were Aware of Available Design Changes that Could Substantially Reduce Failures

89. Bard knew why the design changes made to the Recovery® filter were causing failures.

90. Bard was aware that the diameter of the leg hooks was a substantial factor in a filter's ability to resist migration and fatigue.

91. By reducing the diameter of the hooks on the Recovery® filter, Bard had reduced the device's ability to remain stable and not fracture.

92. Bard also reduced the leg span of the Recovery® filter from that of the SNF filter by 25%. As a result, Bard knew its retrievable IVC filters lacked a sufficient margin of safety to accommodate expansion of the vena cava (distension) after placement.

93. Bard was also aware that its failure to electropolish the wire material prior to distribution meant that Bard IVC Filters had surface damage that reduced their fatigue resistance.

94. Bard was also aware that the Recovery® filter had a high propensity to tilt and perforate the vena cava, which substantially increased the risk of fracture.

95. Bard was also aware that fatigue resistance could be increased by decreasing the sharpness of the angle of the wire struts where they exited the cap at the top of the IVC filters, and by chamfering (rounding or reducing the sharpness) of the cap edge against which the struts rubbed.

96. A few examples of Bard's awareness of the unreasonably dangerous problems with Bard IVC Filters include:

a. On June 18, 2003, BPV engineer Robert Carr sent an email noting that chamfering the edge of the cap would reduce the likelihood of fracture.

b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage seen on the Recovery® filter from the manufacturing process decreases fatigue resistance and that electropolishing increases fatigue resistance.

c. In an April 2004 meeting, BPV was warned by its physician consultants, Drs. Venbrux and Kaufman, that the migration resistance of the Recovery® filter needed to be raised from 50 mmHg to 140 mmHg. They further warned BPV that Bard's Recovery® filter was a "wimpy" filter and its radial force was inadequate to assure stability.

d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to the filter would "address the arm fracture issue."

e. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery® filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery® filter with a small chamfer broke after ten bending cycles.

97. Prior to Plaintiffs being implanted with a Bard IVC Filter, Bard was aware of other design changes that could make the Recovery® filter substantially safer. In a report dated February 16, 2005, BPV describes the design changes to the Recovery® filter, which became known as the

G2® Filter. The report states that the Recovery® filter has been modified to "to increase migration and fracture resistance, and to minimize the likelihood of leg twisting, appendage snagging, filter tilting, and caval perforation." The document goes on to describe the design modifications, which include:

a. Increased ground wire diameter of the hook from .0085" to .0105" in order to improve the fracture resistance of the hook and to improve the migration resistance of the filter.

b. The leg span has been increased from 32mm to 40mm in order to improve the ability of the filter to expand with a distending vena cava reducing risk of migration.

c. The total filter arm length has increased from 20mm to 25mm, enlarging the arm span from 30mm to 33mm to aid in filter centering.

d. An additional inward bend has been applied to the end of the filter arm in order to improve arm interaction with the vessel wall and to address caval perforations and appendage snagging.

e. The arc of filter arm, as it attaches to the sleeve, has been modified to have a smooth radial transition instead of sharp angle. This change was made in order to reduce the stress concentration generated by the sharp angle and thus improve fracture resistance in the area of the filter.

f. The report concludes that the design modifications have substantially reduced the risk of fracture.

98. Subsequent design changes only marginally improved product safety, but did not fully or adequately address the Bard IVC Filters' deadly defects.

99. Electropolishing was added to the Bard IVC Filters in 2010 to reduce the risk of fracture. Electropolishing implanted Nitinol IVC filters was the industry standard, and increased fatigue resistance by at least 25%, according to Bard's internal testing.

100. Additional anchors were added to the anchoring system on the filter in 2011, in what became known as the Meridian filter. The purpose of this improvement was to decrease the risk of tilting, which increases the risk of fracture and perforation, and reduce caudal migration.

101. Bard added penetration limiters with the introduction of Denali Filter in May 2013.

102. Penetration limiters are designed to reduce perforation and penetration of the vena cava.

D. Bard Misrepresented and Concealed the IVC Filters' Risks and Benefits

103. Despite knowing that the Recovery® filter was substantially more likely to fracture, migrate, tilt, and cause death than any other filter, Bard marketed its IVC Filters as being safer and more effective than all other filters throughout the lifecycle of the product.

104. Bard further provided mandatory scripts to its Bard IVC filter sales force, which required the sales force to falsely tell physicians that the Recovery® filter was safe because it had the same reported failure rates as all other filters.

105. Even Bard's updated labeling in December 2004 downplayed and concealed the Recovery® filter's dangerous effects because it suggested fractures almost always cause no harm and that all filters had the same risk of failure.

106. Bard's updated labeling also downplayed the risk of harm by stating that serious injuries had only been "reported" when Bard knew such injuries had in fact occurred.

E. Bard Chose to Keep Selling an Unsafe IVC Filter and Lied to Its Own Sales Force to Ensure Market Share and Stock Prices

107. Instead of warning the public or withdrawing the IVC Filters from the market to fix the problems with its IVC filters, Defendants retained a public relations firm, opened a task force to prevent information from getting out to the public, and devised a plan to address the public if it did.

108. In 2004, Bard created a Crisis Communication Team that included members of Bard's upper level management, Bard's legal department, and independent consultants.

109. The Crisis Communication Team created a Crisis Communication Plan, which summarized Bard's motivation for withholding risk information from the public as follows:

> The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

110. In an April 2004 email, BPV consultant Dr. John Lehmann, a member of the Crisis Communication Team, advised Bard to conceal from the public Bard's information about the material risk of Bard IVC filters. Bard adopted his advice. His email states, among other things:

> Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard. That "Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the IVC Filters currently marketed in the U.S., including the Recovery IVC Filters.
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> ***
>
> I wouldn't raise this subject if at possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that although RF was certainly within the boundaries of IVC Filters tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors.

111. Bard also made false representations and/omissions to the BPV sales force to keep them selling the IVC filters. Bard reassured the sales force that despite the failures with the Recovery® filter, the Bard IVC Filters were safe because they had the same failure rates as all other IVC filters.

112. By December 2004, BPV's own internal safety procedure deemed the Recovery® filter not reasonably safe for human use. Yet Bard continued to market and sell the Recovery® filter into September 2005 and continued to allow its defective product to sit on shelves available to be implanted for an unknown period of time after September 2005.

113. Even after the G2® filter was launched in September 2005, Bard still failed to warn consumers of the increased risk posed by the Recovery® filter. Indeed, in 2006, as reported fracture and associated injury rates were climbing, Bard considered a recall or warning letter that would have provided reported failure rates. The stated benefit of this action was the avoidance of ongoing fractures and related injuries. However, Bard again chose to conceal information about the serious risks of substantial harm from the use of its defective product.

THE G2®, G2® EXPRESS, and G2X® FILTERS

114. On or about March 2, 2005, Bard submitted a Section 510(k) premarket notification of intent to market the G2® filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. In doing so, Bard cited the Recovery® filter as the substantially equivalent predicate IVC filter. Bard stated that the only differences between the Recovery® filter and the G2® filter were primarily dimensional, and no material changes or additional components were added. It was considered by Bard the next generation of the Recovery® filter.

115. On March 30, 2005, however, the FDA rejected this application unless Bard and BPV included "black box" warnings that read:

> Warning: The safety and effectiveness of the Recovery® Filter System in morbidly obese patients has not been established. There have been fatal device-related adverse events reported in this population.
>
> [and]
>
> [C]entral venous lines may cause the filters to move or fracture.

116. On April 25, 2005, Bard's Marketing Director emailed Bard Regulatory Affairs to tell them that such a black box warning would effectively deny morbidly obese patients from having the benefit of Bard's filter.

117. On April 19, 2005, prior to formally responding the FDA's request to add a black box warning, Bard CEO Timothy Ring and Bard President and COO John Weiland received an executive summary reporting that there were at least 34 migrations and 51 fractures associated with Bard IVC Filters.

118. This same report advised Bard executives that there were then nine deaths, six of which related to morbidly obese patients. Further, 18 of the 51 fractures resulted in fragments migrating to the heart.

119. On April 20, 2005, without alerting the FDA to the alarming information Bard executives had the day before, Bard submitted a letter in response to the FDA's request to add this black box warning stating that, "There is currently a statement in the IFU linking all of our complications to death."

120. On August 29, 2005, the FDA cleared the G2® filter for the same intended uses as the Recovery® filter, except that it was not cleared for retrievable use.[1] Contrary to the FDA's suggestion, no black box warning was added to warn the bariatric patient population of fatalities associated with the use of the filter.[2]

121. In September of 2005, Bard quietly and belatedly replaced the Recovery® filter on hospital shelves with the G2® filter. Bard either told doctors or led them to believe that the G2® was a new and improved version of the Recovery® filter with the same option to retrieve the filter after implant.

122. At the same time Bard was selling the G2® (then a permanent-use filter without any retrievability option), Bard was also selling the SNF, which had the same indication for use with nearly zero adverse events.

123. Bard marketed the G2® filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance" without any data to back up these representations. Even if such data existed, Bard witnesses have testified that Bard would not share any such information with doctors if requested.

124. Moreover, as with its predecessor Recovery® filter, Bard failed to conduct adequate clinical and bench testing to ensure that the G2® filter would perform safely and effectively once implanted in the human body.

125. The G2® filter's design causes it to be of insufficient integrity and strength to withstand normal stresses within the human body so as to resist fracturing, migrating, and/or tilting, and/or perforating the inferior vena cava.

126. In addition to the same design defects as its predecessor device, the G2® filter suffers from the same manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of Bard IVC Filters. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2® filter while *in vivo*.

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[1] The FDA did not clear the G2® filter to be used as a retrievable filter until January 15, 2008.

[2] A warning was eventually added to the IFU in October of 2009.

127. In particular, the G2® filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the IVC Filters.

128. Put simply, the G2® filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes Bard IVC Filters more susceptible to fatigue, failure, and migration.

129. Similarly, although Bard rounded the chamfer at the edge of the cap of the G2® filter, it continued to fracture at that same location.

130. Thus, the G2® filter shares similar defects and health risks as the Recovery® filter.

131. Almost immediately upon the release of the G2® filter, Bard received notice of the same series of adverse events of migration, fracture, tilt, and perforation causing the same type of harm as the Recovery® filter. This time, however, a new and different adverse event emerged: the G2® filter would caudally (moving against blood flow) migrate in the direction toward the groin.

132. The G2® filter failures were again associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

133. Bard represents the fracture rate of the G2® filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true frequency of fractures for the G2® filter.

134. As with the Recovery® filter, Bard was aware of clinical data showing that the G2® filter was not the substantial equivalent of its predecessor SNF device, requiring immediate recall of the adulterated and misbranded product.

135. A review of the MAUDE database from the years 2004 through 2008 demonstrates that the Bard IVC Filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to IVC filters.

136. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard was even selling the modified version of the Recovery® filter, when Bard's SNF had virtually no complaints associated with it.

137. This further confirms the misbranded and adulterated nature of the device, requiring corrective action, including recall.

138. On January 15, 2008, the FDA allowed a retrievable option for the G2® filter, the G2 Express® filter. The G2 Express® filter is identical in design to the G2® filter except that it has a hook at the top of the filters that allows it to be retrieved by snares, as well as Bard's Recovery Cone.

139. The G2 Express® filter contained no design modifications or improvements to alleviate the instability, structural integrity, and perforation problems that Bard knew to exist with the G2®X Filter via the 510(k) process.

140. On information and belief, Bard subsequently designed and marketed the G2®X filter. On information and belief, the G2®X filter is substantially identical in design to the G2 Express® filter.

141. On information and belief, the G2®X filter contained no design modifications or improvements to alleviate the instability, structural integrity, and perforation problems that Bard knew to exist with the G2®X Filter via the 510(k) process.

THE ECLIPSE® FILTER

142. In a failed effort to resolve the complications associated with its previous filters, Bard designed the Eclipse® Vena Cava Filter as the next generation in its retrievable IVC filter family.

143. The Eclipse® filter was cleared by the FDA on January 14, 2010. The only design changes from the G2® family of filters to the Eclipse® filter was that the Eclipse® filter was electropolished.

144. According to Bard's internal testing, electropolishing supposedly increased fracture resistance by 25% and therefore was purportedly a safer alternative to the Recovery® and G2® filter product line.

145. However, longitudinal studies published in peer-reviewed medical literature found that among 363 patients implanted with the Recovery® filter and 658 patients implanted with the G2® filter, the devices experienced fracture rates of 40% and 37.5%, respectively, after five and a half years.

146. Thus, even if the Eclipse® truly was a safer alternative to the Recovery® and G2® filters as Bard claimed, an enormous percentage (approximately 28.125% to 30%) of Eclipse® filters would still be projected to fracture within five and a half years.

147. Without meaningful design changes, the Eclipse® filter continued to share several of the same design defects and complications associated with the Recovery® filter and G2® family of filters.

148. Soon after Bard launched the Eclipse® filter, it began receiving complaints and reports of injuries associated with the Eclipse® filter similar to those received with its predecessor filters.

149. Bard, however, knew and/or soon learned that the Eclipse® filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

THE MERIDIAN® FILTER

150. The Meridian® filter was cleared by the FDA in August of 2011.

151. Bard represented to the FDA that the Meridian was substantially similar to the Eclipse® filter and could therefore be cleared via the less onerous 510(k) process.

152. Bard, however, knew and/or soon learned that the Meridian® filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

153. The Meridian® filter system was the next-generation of Bard's retrievable or optional filters. The Meridian® filter is made of the same nickel-titanium alloy, NITINOL, as the Bard Recovery®, G2®, and Eclipse® filters.

154. The design of the Meridian is based on the Eclipse® filter, which, in turn, is based entirely on the G2® filter, which, in turn, is based on the Recovery® Filter. Like the Eclipse®, the wires used in the Meridian® filter are electropolished prior to the forming of the filter. The only added feature to the Meridian® filter was a caudal anchoring system added in an attempt to reduce the prevalence of the filter caudal migrating toward the groin.

155. This added feature was an attempt to make this design the safer alternative to the Eclipse®, G2®, and Recovery® filters.

156. However, as seen with the Recovery®, G2®, and Eclipse® filters, soon after its introduction to the market reports surfaced that the Meridian® filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

157. The Meridian® filter was also plagued with the same manufacturing and design defects that were causing damage to the general public as Bard's predecessor retrievable filters.

THE DENALI® FILTER

158. The Denali® filter was cleared by the FDA on May 15, 2013. It is Bard's latest generation device in the IVC filter product line.

159. Bard represented to the FDA that the Denali® was substantially similar to the Eclipse® filter, again bypassing formal pre-market FDA approval and instead utilizing the 510(k) process.

160. The Denali® Filter is also made of NITINOL. Its design is based on the Eclipse® filter, which in turn, was based on Bard's predecessor filter line.

161. Like the Eclipse®, the NITINOL wires used in the Denali® filter are electropolished prior to the forming of the filter. The added features to the Denali® Filter were cranial and caudal anchoring systems (to reduce the prevalence of the filter migration) and penetration limiters. These added features were an (unsuccessful) attempt to make this design a safer alternative to the Meridian®, Eclipse®, G2®, G2 Express®, G2X®, and Recovery® filters.

162. However, as seen with the Recovery®, G2®, G2 Express®, G2X®, and Eclipse® Filters, soon after its introduction to the market, reports were made that the Denali® filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

163. The Denali® filter was likewise plagued with the same manufacturing and design defects that were causing damage to the general public in Bard's predecessor retrievable IVC filter family.

164. At all times material hereto from the design phase, testing, and manufacture of the Recovery® filter through the Denali® filter, Bard lacked a thorough understanding dynamics of caval anatomy that impacted testing methods.

165. At this time, all Bard IVC Filters contain the same or substantially similar defects resulting in the same or substantially similar mechanism of injury to Plaintiffs and their decedents.

166. At this time, all Bard IVC Filters are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor device, making them subject to corrective action, including recall, in the interest of patient safety.

167. At all relevant times, safer and more efficacious designs existed for this product, as well as reasonable treatment alternatives.

168. Bard marketed and sold the IVC Filters as being retrievable but also represented them as being safe for the life of the patient without retrieval, and particularly that they were safe to remain in vivos as permanent devices.

F. FDA WARNING LETTERS AND ADVISORIES

169. On August 9, 2010, the FDA issued an advisory to physicians and clinicians responsible for the care of patients with IVC filters. Noting that it had, as of that date, received 921 device adverse event reports involving IVC filters, the FDA stated that it was "concerned that these retrievable IVC filters, intended for short-term placement, are not always removed once a patient's risk for [pulmonary embolism] subsides. It recommended that physicians and clinicians consider removing the filter as soon as protection from PE is no longer needed."

170. On May 6, 2014, the FDA issued an updated safety communication concerning IVC filters. This communication reported that the FDA had developed a quantitative decision analysis

designed to assess when "the risk of having an IVC filter in place is expected to outweigh the benefits." The FDA published that decision analysis in the Journal of Vascular Surgery: Venous and Lymphatic Disorders, in October 2013. The FDA's "mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation."

171. In late 2014, the FDA conducted inspections of BPV's facilities in Queensbury, New York, and Tempe, Arizona – Bard's IVC filter facilities. Those inspections commenced a nine-month investigation by the FDA.

172. Following the inspections, the FDA issued Bard two Form "483" letters in which it identified various deficiencies and violations by Bard at its IVC-filters facilities.

173. Among the findings of its investigation, the FDA discovered that Bard had reported multiple serious injuries and a death to the FDA MAUDE database as non-injurious "malfunctions."

174. In response to those findings, Bard conducted its own audit of its adverse event reporting to the FDA over a two-year period. That audit found that, out of 939 IVC filter complaint records, Bard had reported 230 serious injuries and deaths as mere "malfunctions." The audit also found that Bard failed to report (at all) an additional 44 adverse events that it should have reported to the FDA and the MAUDE database. Thus, based on its limited audit, Bard had underreported 274 out of 939 adverse events.

175. Bard had the opportunity to respond to the 483 letters and to cure the issues set forth therein. Bard, in fact, submitted several responses to the FDA. However, the FDA found its responses "not adequate"; and Bard ultimately failed to cure the violations.

176. On July 13, 2015, the FDA issued a formal warning letter to Bard, identifying eight separate violations by Bard of the Code of Federal Regulations and that its IVC Filters were adulterated and misbranded under federal law.

177. The FDA notified Bard that its IVC Filters were adulterated and misbranded because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice

requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Section 820, and that Bard failed to comply with adverse event reporting requirements of 21 C.F.R. 803.

178. The FDA cited numerous specific violations, including the failure to establish and maintain procedures to ensure that product complaints are adequately investigated and reported, and a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together. For instance, the FDA cited numerous examples of Bard reporting G2, G2 Express, and Eclipse filter failures resulting in death and other serious injuries as if there was no patient injury involved. The FDA also found that Bard failed to establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture of its filters were reduced to acceptable levels prior to distribution.

PROPOSED NOTICE AND DIAGNOSTIC PROGRAM

179. In its May 2014 safety communication concerning IVC filters, the FDA expressed concerns over the continuing presence of implanted IVC filters in patients. To that end, the FDA recommended that:

> physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed. The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.[3]

180. In October 2013, Guillermo Altonaga, Bard's medical director, testified that IVC filters are a "very delicate device" placed in a "very clinically hostile anatomy" that may come loose if they do not attach well and will be moved by the blood flow of the vena cava. He further testified that IVC filter tilt can pose "significant health risk to the patient and that "how soon it's detected" can affect the risk to patients from a fractured filter.

[3] http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm396377.htm (last visited 1/14/16.)

181. Indeed as early as July 2004, Bard recognized the potential value of monitoring patients implanted with IVC filters. Bard's then-medical director, David Ciavarella, authored a Health Hazard Evaluation regarding Bard's IVC Filters in which he stated that "[m]ore frequent monitoring of the filter once placed may facilitate discovery of abnormal placement … or indeed a fractured filter …."

182. In a Health Hazard Evaluation from June 2004 concerning migration of the Recovery filter, Dr. Ciavarella wrote, "All patients in whom a vena cava filter is placed are at risk for this complication."

183. Internal Bard documents from 2005 and 2006 recognized the need to monitor patients who have been implanted with Bard's IVC Filters.

184. Bard's expert in state court litigation, Dr. Clement J. Grassi, testified in 2014 that he agreed that individuals with Bard's Recovery and G2 filters should be monitored.

185. Despite what Bard knew and stated internally about the benefits of monitoring of individuals with Bard's IVC filters, Bard did not recommend publicly, including in any IFU for any of the filters at issue, or otherwise, that physicians monitor and follow up with their patients with IVC Filters.

186. Against this backdrop, and the massive scale of medical literature indicating that Bard's IVC Filters pose long term risks of migration, fracture, perforation, tilting, and ultimately catastrophic injury or death, Plaintiffs seek a monitoring program designed to evaluate whether the risk/benefit profile of every class member favors removal of the Bard IVC filter and, if so, to gather information on the appearance, condition, and location of the IVC filter, including whether it has fractured, migrated, perforated, or tilted, in order to provide a physician with the information necessary to remove the Bard IVC filter safely.

187. Specifically, Plaintiffs seek a medical monitoring protocol which consists of (1) a notice campaign to all Class members informing them of the availability and necessity of the medical motoring protocol and (2) a "catheter venography" to be performed on every class member who still has a Bard IVC filter installed by an interventional radiologist who will then consult with the class member's physician to determine if retrieval is clinically necessary and, if so, to provide

the physician with necessary information regarding how much force to exert in removing the Bard IVC filter (the "Medical Monitoring Protocol"). In addition to the assessment of the condition and removal prospects of the Bard IVC filter, specific attention to the particularized and high incidence of defect must be considered before they are removed.[4]

188. Dr. Myerburg, writing in the New England Journal of Medicine, noted that with implantation of medical devices that have a demonstrated failure rate leading to death, (1) "tolerance and surveillance strategies should aim to achieve a risk of malfunction that is as close to zero as possible"; (2) that "physicians must know about the performance features of [the] device"; and (3) "patients have a right to obtain product information so that they can make informed decisions."[5] Plaintiffs' proposed Medical Monitoring Protocol aims to reduce complications by aiding in the detection and remediation of any malfunction and also generally provides awareness of the issue so it can be investigated. Without this protocol, many if not most patients implanted with these IVC Filters will not even be aware of the serious risk they are in.

189. Additionally, medical literature notes that "there appears to be no long-term survival benefit from long-term filter implantation…" and "lack of adequate follow-up evaluation for device retrieval may also contribute to inadvertent chronic filter implantation."[6] Dr. Kuo and his co-authors also note that "When IVC filtration is no longer required, we believe prompt filter retrieval is desired if it can be performed with reasonable safety to avoid the risk of complications from long-term implantation." Plaintiffs' proposed Medical Monitoring Protocol is designed to evaluate the risk of long-term implantation in association with the need and possibility of removal by offering Class Members an individual evaluation of their circumstances while educating them on the risks of the IVC Filter currently implanted in their vena cava.

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[4] Kaufman J., et al., Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. -Journal of Vascular and Interventional Radiology 2006, 17:449-459.

[5] Myerburg R., et al., Life-Threatening Malfunction of Implantable Cardiac Devices. The New England Journal of Medicine 2006; 354:22.

[6] Kuo W., et al., High-risk Retrieval of Adherent and Chronically Implanted IVC Filters; Techniques for Removal and Management of Thrombotic Complications. Journal of Vascular and Interventional Radiology 2009, 20:1548-1556.

Fraudulent Concealment

190. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Bard when they had a duty to disclose those facts. Defendants have kept Plaintiffs and their physicians ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiffs' part, for the purpose of obtaining delay on Plaintiffs' part in filing on their causes of action. Bard's fraudulent concealment did result in such delay.

191. Bard is estopped from relying on the statute of limitations defense because Bard failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery®, G2®, G2 Express, G2X, Eclipse®, Denali, and Meridian Filter Systems.

192. Plaintiffs and Plaintiffs' health care providers could not reasonably have discovered the claims made herein until at the earliest the devices were discovered to have malfunctioned.

193. Bard was under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiffs, but instead they concealed them. Bard's conduct, as described in this Complaint, amounts to conduct purposely committed, which Bard must have realized was dangerous, needlessly reckless, without regard to the consequences or the rights and safety of Plaintiffs.

Class Action Allegations

194. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2), and (c)(4) as representatives of classes defined as follows:

195. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, the class representative plaintiffs for their particular state class on behalf of themselves and all others similarly situated, seek certification of the classes defined as follows (collectively, the "Class"):

a. **Arizona**: All residents of the state of Arizona who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter

System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

b. **California**: All residents of the state of California who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

c. **Colorado**: All residents of the state of Colorado who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

d. **Washington, D.C.**: All residents of the District of Columbia who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

e. **Florida:** All residents of the state of Florida who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

f. **Guam:** All residents of Guam who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

g. **Illinois:** All residents of the state of Illinois who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

h. **Indiana:** All residents of the state of Indiana who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

i. **Maryland:** All residents of the state of Maryland who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

j. **Massachusetts:** All residents of the Commonwealth of Massachusetts who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

k. **Missouri:** All residents of the state of Missouri who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

l. **Nevada:** All residents of the state of Nevada who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC

filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

m. **Ohio:** All residents of the state of Ohio who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

n. **Pennsylvania:** All residents of the state of Pennsylvania who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

o. **Utah**: All residents of the state of Utah who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

p. **West Virginia:** All residents of the state of West Virginia who, between July 25, 2003 and the date of the filing of this complaint, were implanted with one or more of the following IVC filters – Recovery Filter System, G2 Filter System, G2 Express Filter System, the G2X Filter System, Meridian Filter System, or Denali Filter System – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the these IVC filters.

Excluded from these classes are Defendants and their subsidiaries and affiliates, as well as the judicial officers and their staff to whom this is assigned or referred, and their immediate family members.

196. The members of the Class are so numerous that joinder is impracticable. Thousands of Class members have been implanted with the IVC Filters and have not filed a claim or lawsuit alleging personal injury relating to the IVC Filters.

197. This case presents numerous questions of law or fact that are common to all Class members. These questions' answers are central to the validity of Plaintiffs' and Class members' claims, and their determination is apt to drive the resolution of the claims. These common questions include:

a. Whether the IVC filters manufactured and sold by Bard have design defects;

b. Whether Defendants acted negligently in the design, manufacturing, marketing, and sale of the IVC Filters at issue;

c. Whether Plaintiffs have been exposed to increased or significantly increased risk of injury as a result of the implantation of the IVC Filters at issue;

d. Whether a Court-supervised notice and diagnostic program should be established to mitigate or reduce the risk of injury as a result of the implantation of the IVC Filters at issue; and

e. What a medical monitoring program that is consistent with the standard of care and with contemporary scientific principles would entail.

198. Plaintiffs' claims are typical of the claims of those of Class members, as they all arise from the same common course of conduct on the part of Defendants.

199. Plaintiffs will fairly and adequate protect the interests of the Class. Plaintiffs' interests are aligned with and not in conflict with those of Class members. Plaintiffs and the Class are represented by counsel with long and deep experience in the prosecution of class actions, including those relating to product defects, including medical devices, medical negligence, personal injury, and medical monitoring. Plaintiffs' counsel is knowledgeable about the applicable law and possesses the resources to fully commit to representing the Class.

200. Defendants have acted and have refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief, in the form of medical monitoring, is appropriate respecting the class as a whole.

201. Questions of law or fact common to Class members predominate over any questions affecting only individual Class members.

202. A class action is superior to other available methods for fairly and efficiently adjudicating these claims.

203. This case involves numerous common issues that can be resolved on a classwide basis, and which issues predominate over any individualized issues. These include:

a. Whether the IVC filters manufactured and sold by Bard have design defects;

b. Whether Defendants acted negligently in the design, manufacturing, marketing, and sale of the IVC Filters at issue;

c. Whether Plaintiffs have been exposed to increased or significantly increased risk of injury as a result of the implantation of the IVC Filters at issue;

d. Whether a Court-supervised notice and diagnostic program should be established to mitigate or reduce the risk of injury as a result of the implantation of the IVC Filters at issue; and

e. What a diagnostic/medical monitoring program that is consistent with the standard of care and with contemporary scientific principles would entail.

CAUSE OF ACTION
MEDICAL MONITORING
(ON BEHALF OF COLORADO, DISTRICT OF COLUMBIA, FLORIDA, GUAM, ILLINOIS, PENNSYLVANIA, UTAH, AND WEST VIRGINIA CLASSES)

204. Plaintiffs repeat and incorporate by reference each of the foregoing allegations of this Complaint.

205. The following jurisdictions recognize medical monitoring as an independent claim for relief: Colorado, District of Columbia, Florida, Guam, Illinois, Pennsylvania, Utah, and West Virginia.

206. Plaintiffs were exposed to a significantly higher risk of injury and death from Bard's IVC Filters than they would have faced if they had the filters been designed without defect, had Bard given appropriate and adequate warnings regarding the risks of the IVC Filters, or had Plaintiffs received alternative forms of treatment. As a result, Plaintiffs are and will be exposed to

a significant risk of injury and death on an ongoing basis as a result of Defendants' negligent conduct.

207. Defendants were fully aware of yet failed to adequately warn, protect, and educate Plaintiffs concerning these increased risks.

208. Defendants had a duty to provide necessary and adequate warnings of the increased risks of the IVC Filters. By such negligent conduct, Defendants breached their duties of care to the Plaintiffs and members of the Class, and caused significantly increased risk of injury and damages to Plaintiffs, giving rise to the need for diagnosis, assessment, and/or monitoring of the IVC filter.

209. As a proximate result of Defendants' negligent conduct, Plaintiffs have experienced and been exposed to significantly increased risks of injury from the IVC Filters (including the devices' migration, tilting, fracturing, and perforation of the vena cava), including hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels, and organs; and death.

210. Diagnostic and/or monitoring procedures exist that comport with contemporary scientific principles and the standard of care and make possible early detection of potential injury to Plaintiffs and Class members, which would not be possible without such diagnostic and/or monitoring procedures. The proposed Court-supervised diagnostic and/or monitoring program includes, but is not limited to, baseline exams and diagnostic exams. This program is necessary and includes more monitoring than will be typically provided to Class members in order to detect, prevent, and mitigate injury that may occur if treatment was delayed, and enable prompt treatment of the adverse consequences of the IVC Filters.

211. The program and procedures set forth above are non-routine, and are fundamentally different from and more extensive than the normally prescribed medical treatment and/or diagnostic procedures for those with IVC Filters, including non-defective devices.

212. The diagnostic and/or monitoring procedures proposed by this action are reasonably necessary for all Plaintiffs and Class members because all Plaintiffs and Class members have been implanted with the IVC Filters, which present significantly increased risks of the same injuries and

harm, including possibly death, to Plaintiffs and Class members by the same mechanisms and modes of failure.

213. As set forth above, the Court-supervised monitoring procedures are reasonably necessary according to contemporary scientific principles to enable Plaintiffs to obtain early detection and diagnosis of the potential injury and increased risk of injury as a result of the implantation of the IVC Filters described above.

214. By monitoring and testing Plaintiffs who are at increased risk of injury from the IVC Filters, the risk of Class members suffering injury, disease, and losses as described above may be significantly reduced, as Class members and their physicians will have gained information necessary to choose appropriate interventions and treatments.

215. Plaintiffs therefore seek an injunction creating a Court-supervised comprehensive medical monitoring fund for Plaintiffs and the Class, which would facilitate the early diagnosis and treatment in the event of future injury to Plaintiffs and Class members.

216. Accordingly, Defendants should be required to establish a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class members, which includes, among other things: (1) a notice campaign to all Class members informing them of the availability and necessity of the medical motoring protocol and (2) a "catheter venography" to be performed on every Class member who still has a Bard IVC filter installed by an interventional radiologist who will then consult with the Class member's physician within 60 days to determine if retrieval is clinically necessary and, if so, to provide the physician with necessary information regarding how much force to exert in removing the Bard IVC filter.

217. Defendants' negligent conduct has caused significant increased risk, as described above, that the law of these states recognizes as an injury to legally protected rights, giving rise to claims for injunctive/equitable relief. The distribution of damages to individual class members without programmatic relief as described above is inadequate, inefficient, and/or inferior to a judicial injunctive, declaratory, or equitable degree, establishing and supervising class-wide medical monitoring services as described and as sought herein. Plaintiffs have no adequate remedy

at law, in that monetary damages cannot compensate them for the increased risks of long-term physical and economic losses associated with future injury from the IVC Filters, or the uncertainty associated with living with a defective and dangerous medical device. Without a Court-supervised comprehensive medical monitoring fund as described herein, Plaintiffs will continue to face increased risks of injury without proper diagnosis and opportunity for rehabilitation.

CAUSE OF ACTION
NEGLIGENCE/MEDICAL MONITORING
(ON BEHALF OF MEMBERS OF ARIZONA, CALIFORNIA, INDIANA, MARYLAND, MASSACHUSETTS, MISSOURI, NEVADA, AND OHIO CLASSES)

218. Plaintiffs repeat and incorporate by reference each of the foregoing allegations of this Complaint.

219. The following jurisdictions recognize medical monitoring as a remedy and/or recoverable item of damages for negligent or tortious conduct: Arizona, California, Indiana, Maryland, Massachusetts, Missouri, Nevada, and Ohio.

220. Plaintiffs were exposed to a significantly higher risk of injury and death from the IVC Filters, and will be exposed to injury and death on an ongoing basis as a result of Defendants' negligent conduct.

221. Defendants were fully aware of yet failed to adequately warn, protect, and educate Plaintiffs concerning these increased risks.

222. Defendants had a duty to provide necessary and adequate warnings of the increased risks of the IVC Filters. By such negligent conduct, Defendants breached their duties of care to the Plaintiffs and members of the Class, and caused significantly increased risk of injury and damages to Plaintiffs, giving rise to the need for diagnosis, assessment, and/or monitoring of the IVC filter.

223. As a proximate result of Defendants' negligent conduct, Plaintiffs have experienced and been exposed to significantly increased risks of injury from the IVC Filters (including the devices' migration, tilting, fracturing, and perforation of the vena cava), including hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels, and organs; and death.

224. Diagnostic and/or monitoring procedures exist that comport with contemporary scientific principles and the standard of care and make possible early detection of potential injury to Plaintiffs and Class members, which would not be possible without such diagnostic and/or monitoring procedures. The proposed Court-supervised diagnostic and/or monitoring program includes, but is not limited to, baseline exams and diagnostic exams. This program is necessary and includes more monitoring than will be typically provided to Class members in order to detect, prevent, and mitigate injury that may occur if treatment was delayed, and enable prompt treatment of the adverse consequences of the IVC Filters.

225. The program and procedures set forth above are non-routine, and are fundamentally different from and more extensive than the normally prescribed medical treatment and/or diagnostic procedures for those with IVC Filters, including non-defective devices.

226. As set forth above, the Court-supervised monitoring procedures are reasonably necessary according to contemporary scientific principles, to enable Plaintiffs to obtain early detection and diagnosis of the potential injury and increased risk of injury as a result of the implantation of the IVC Filters described above.

227. By monitoring and testing Plaintiffs who are at increased risk of injury from the IVC Filters, the risk of Class members suffering injury, disease, and losses as described above may be significantly reduced, as Class members and their physicians will have gained information necessary to choose appropriate interventions and treatments.

228. Plaintiffs therefore seek an injunction creating a Court-supervised comprehensive medical monitoring fund for Plaintiffs and the Class, which would facilitate the early diagnosis and treatment in the event of future injury to Plaintiffs and Class members.

229. Accordingly, Defendants should be required to establish a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class members, which includes, among other things: (1) a notice campaign to all Class members informing them of the availability and necessity of the medical motoring protocol and (2) a "catheter venography" to be performed on every Class member who still has a Bard IVC filter installed by an interventional radiologist who will then consult with the Class member's

physician within 60 days to determine if retrieval is clinically necessary and, if so, to provide the physician with necessary information regarding how much force to exert in removing the Bard IVC filter.

230. Defendants' negligent conduct has caused significant increased risk, as described above, that the law of these states recognizes as an injury to legally protected rights, giving rise to claims for injunctive/equitable relief. The distribution of damages to individual class members without programmatic relief as described above is inadequate, inefficient, and/or inferior to a judicial injunctive, declaratory, or equitable degree, establishing and supervising class-wide medical monitoring services as described and as sought herein. Plaintiffs have no adequate remedy at law, in that monetary damages cannot compensate them for the increased risks of long-term physical and economic losses associated with future injury from the IVC Filters, or the uncertainty associated with living with a defective and dangerous medical device. Without a Court-supervised comprehensive medical monitoring fund as described herein, Plaintiffs will continue to face increased risks of injury without proper diagnosis and opportunity for rehabilitation.

Prayer for Relief

WHEREFORE, Plaintiffs pray for relief as follows:

1. This action to be certified as a class action on behalf of the proposed classes; that the named plaintiffs be appointed as Class representatives, and that counsel below be designated Class Counsel;

2. Creation of a comprehensive, Court-supervised notice and diagnostic/medical monitoring program for the proposed classes;

3. Judgment to be entered against all Defendants on all causes of action and damages suffered;

4. Plaintiffs be awarded the full, fair, and complete recovery for all causes of action;

5. Plaintiffs be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest, as authorized by law; and

6. Such other relief that the Court deems just and proper.

Jury Trial Demand

Plaintiffs request a jury trial on all questions of fact raised by this Complaint.

Dated: ~~December 19, 2016~~ January __, 2017

Respectfully submitted,

ON BEHALF OF PLAINTIFFS AND THE PROPOSED CLASS

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